

Notice of Allowability

Application No.

10/705,716

Applicant(s)

ROBINSON ET AL.

Examiner

Art Unit

Anand U. Desai, Ph.D.

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to December 12, 2006.
2. ☒ The allowed claim(s) is/are 8-12 and 38-42.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

1. This office action is in response to Amendment filed on December 12, 2006. Claims 8-12, and 38-42 are currently pending and are under examination.

Withdrawal of Rejections

2. The rejection of claims 8-12 and 38-42 under 35 U.S.C. 102(a) as being anticipated by Tanner et al. (PNAS 98(24): 13901-13906 (Nov. 20, 2001)) is withdrawn based on the filing of a 37 C.F.R 1.131 declaration.

EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dr. Jeffrey B. Safran on February 28, 2007.

Examiner's amendment to the claims:

Claims 1-7, 13-37, 43-88 are cancelled.

Claim 8 (Currently Amended) An isolated polypeptide encoded by an isolated nucleic acid fragment ~~encoding a parathyroid hormone anabolic induced gene in bone~~ polypeptide selected from the group consisting of:

- (a) an isolated nucleic acid fragment encoding SEQ ID NO: 2;

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(b) an isolated nucleic acid fragment encoding an amino acid sequence having at least 98% identity with SEQ ID NO: 2;

(c) an isolated nucleic acid fragment ~~molecule~~ that hybridizes with the isolated nucleic acid fragment of (a) under hybridization conditions of 6x SSC (1M NaCl), 45 to 50 % formamide, 1% SDS at 37 °C, and a wash in 0.5x to 1x SSC at 55 to 60 °C; and

~~(d) an isolated nucleic acid fragment that is complementary to (a), (b), or (c).~~
wherein said polypeptide is parathyroid hormone anabolic induced gene in bone (PAIGB) polypeptide and has osteoblast bone forming activity in bone tissues.

Claims 9 through 12 replace "Claim 8" with --claim 8--.

Claim 39. (Currently Amended) A composition according to ~~Claim~~ claim 38, wherein said parathyroid hormone anabolic induced gene in bone polypeptide is from human osteoblast cells.

Claim 40. (Currently Amended) A composition according to ~~Claim~~ claim 38, wherein the bone forming activity is the regulation of bone growth.

Claim 41. (Currently Amended) A composition according to ~~Claim~~ claim 38, wherein the bone forming activity is the regulation of bone density.

Claim 42. (Currently Amended) The composition according to ~~Claim~~ claim 38, wherein the parathyroid hormone anabolic induced gene is bone polypeptide has the amino acid sequence set forth in SEQ ID NO: 2.

Allowable Subject Matter

4. Claims 8-12, and 38-42 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

February 28, 2007



KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER